REMARKS

Reconsideration of the above-identified application in view of the amendments above and the remarks following is respectfully requested.

Claims 134-177 are pending in this Application. Claims 134-151, 154, 158-163, 165, 166 and 170-177 have been rejected under 35 U.S.C. §102. Claims 152, 153, 155, 156, 157 and 167-169 have been rejected under 35 U.S.C. § 103. Claims 135-137, 143-148, 154-157, 166-169 and 176-177 have been canceled herewith. Claims 134, 149, 158, 163 and 172 have been amended herewith. New claims 178-180 have been added herewith.

35 U.S.C. § 102 Rejections

The Examiner has rejected Claims 134-140, 143-146 and 172-177 under 35 U.S.C. 102(b) as being anticipated by Desai et al (U.S. 5,550,178). The Examiner states that Desai et al teaches methods of preparing a biodegradable film comprising crosslinked PEG, crosslinked alginate and further comprising a drug.

The Examiner's rejection is traversed.

Claims 135-137, 143-146 and 176-177 have now been cancelled rendering Examiner's rejection mute.

Applicant wishes to point out that Desai et al does not teach a film but a gel-like substance that can be formed into capsules or droplets (see page 16, lines 43-47 of Desai et al).

In sharp contrast to the gels of Desai, the presently claimed films have unique swelling properties, such that on hydration there is only minimal swelling along the axial direction.

In order to further distinguish the presently claimed films from the gels of Desai, Claim 134 has now been amended to include the limitation of comprising a radial swelling ratio upon hydration of about 1.

Support for this claim amendment may be found on Page 28, lines 18-20 and Table 2, Page 29.

To further distinguish the currently claimed films from the gels of Desai et al Claims 178-180 have now been added such that the length of the films is limited to

10-150 mm. This is in sharp contrast to the gels of Desai which speaks of gel droplets being between 200-700 microns in diameter – see page 16, line 30.

Support for the amendment "10-150 mm in length" can be found in the instant specification – see page 13, line 23; and page 13, line 29.

The unique swelling properties of the presently claimed films can be attributed to its method of preparation, whereby, crosslinking of the film is effected on a dry layer of alginate and PEG. The drying stage confines the geometry of the polymer network such that subsequent hydration will not cause swelling in the axial direction.

Claim 172 has now been amended to include the limitation of drying.

Support for this amendment may be found on Page 17, lines 27-31.

Desai et al do not teach films which undergo limited swelling in the axial direction upon hydration, nor methods of producing such films and therefore, and cannot anticipate, alone or in combination with other references, the methods of the present invention. Applicant therefore requests withdrawal of the rejection.

The Examiner has rejected Claims 134, 141, 142, 147-151, 154, 158-163, 165, 166, 170 and 171 under 35 U.S.C. 102(b) as being anticipated by Tartaglia et al (U.S. 5,637,113). The Examiner states that Tartaglia et al teaches expandable stent covered by a polymer film including cross-linked PEG.

The Examiner's rejection is traversed.

Notwithstanding, please note that Claims 134, 149 and 163 has now been amended such that the claimed film comprises both crosslinked PEG and alginate.

Claims 147, 148, 154, 166 have now been cancelled rendering moot Examiner's rejections to these claims.

35 U.S.C. § 103 Rejections

The Examiner has rejected Claims 152, 153, 155, 156, 157 and 167-169 under 35 U.S.C. 103(a) as being obvious over Tartaglia et al (US 5,637,113) in view of Desai et al (US 5,550,178).

The Examiner states that Tartaglia discloses a polymer film deployed by a balloon expandable stent, but does not disclose the stent being self-expandable. Since Tartaglia discloses that the stent comprises a nickel-titanium alloy, a known shape memory polymer, it would have been obvious to someone of ordinary skill in the art to exploit the shape memory characteristics of the nitinol stent to make the stent self-

expandable, being that both nitinol and self expandable nitinol are well known in the art.

The Examiner further states that although Tartaglia does not disclose that the film is biodegradable or comprises alginate, Desai discloses a polymer film having these characteristics. The Examiner concludes that it would have been obvious to deploy the film of Desai using the system of Tartaglia since both Desai and Tartaglia disclose films that are useful in delivering therapeutic drugs to target blood vessel sites.

The Examiner's rejection is traversed.

Please note that Claims 155-157 and 167-169 have now been cancelled, rendering the Examiner's rejection to these claims mute.

As established above, Desai does not teach films which undergo limited swelling in the axial direction, but a composition which is a gel useful for encapsulating biologics, including drugs and cells. Accordingly, one of ordinary skill in the art would not contemplate using the composition of Desai to replace the films taught by Tartaglia since they do not possess the basic characteristics of being useful for endoluminal applications, namely not swelling in the axial direction.

The instant specification teaches that the films comprise unique swelling properties and comprises a radial swelling ratio upon hydration of about 1 – see page 29, Table 2. The instant specification teaches that it is these swelling properties that make the film particulary desirable for coating of blood vessel lumens - see page 11, lines 13-19. Desai et al do not teach of these unique swelling properties and accordingly one of ordinary skill in the art would not think to deploy the films of Desai for coating of lumens of blood vessels. Furthermore, the compositions of Desai would not inherently comprise these swelling properties, since they were not dried prior to polymerization. In addition, the present specificaiton teaches an optimal amount of $CaCl_2$ of about 15 % (page 29, line 15) for instilling these properties into the film and Desai teaches an amount of $CaCl_2$ of about 0.4 % (Page 16, lines 33-35 of Desai et al).

In conclusion, Applicant contends that the Examiner has not provided a motivation to combine the elements nor a reasonable expectation that once combined, the recited elements would function to generate a film useful for endoluminal applications.

In view of the above remarks it is respectfully submitted that claims 134, 138-142, 149-153, 158-165, 170-175 and 178-180 are novel and not obvious and are in condition for allowance. A prompt notice of allowance is respectfully and earnestly solicited.

Respectfully submitted,

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Enclosure:

- Additional Claims Transmittal Fee